AUG 2 4 2001

K012445
PG. 1 OF 3

510(k) Summary
for
Electro Medical Systems SA
SWISS LITHOCLAST® MASTER

1. SPONSOR

ELECTRO MEDICAL SYSTEMS SA
Chemin de la Vaurpilliere 31
CH-1260 Nyon
Switzerland

Contact Person: Giani Campana
Quality Manager

Date Prepared: July 31, 2001

2. DEVICE NAME

Trade/Proprietary Name:	EMS Swiss LithoClast® Master (a.k.a. Swiss LithoClast® Ultra
Common/Usual Name:	Endoscopic intracorporeal pneumatic and ultrasonic lithotripsy
Classification Name:	Electrohydraulic lithotripsy

3. INTENDED USE

The EMS Swiss LithoClast® Master is intended for the intracorporeal fragmentation of ureteral calculi in the kidney, ureter, and bladder.

4. DEVICE DESCRIPTION

The Swiss LithoClast® Master is a modified version of the Swiss LithoClast® previously cleared under K951531 and K963285. Three possible modes of operation are available using the Swiss LithoClast® Master: (1) pneumatic lithotripsy alone; (2) ultrasound lithotripsy alone; (3) and combined pneumatic and ultrasound lithotripsy.

The system consists of two independent operating units in one housing, which allows for independent operation of the two modalities. Delivery of energy is controlled using a common two-pedal footswitch.

The pneumatic unit of the system is essentially the same as the Swiss LithoClast®. Operation of this unit requires a supply of medical quality compressed air from either a compressor or a central hospital supply. The compressed air provides the pressure pulse that drives the projectile within the Swiss LithoClast® handpiece toward the proximal end of the probe. The pressure pulse propagates to the distal tip of the probe and is transferred to the stone, resulting in fragmentation. The pneumatic unit can also be used in combination with the Swiss LithoVac® for suction of stone fragments. The LithoClast® probes can be inserted through the LithoVac® probes for simultaneous lithotripsy and suction.

The ultrasound handpiece consists of an ultrasound transducer containing the piezo-electric elements, which are driven by a generator operating at approximately 24 kHz. The resulting longitudinal waves are propagated along the ultrasound probe to the target stone. The ultrasound transducer and probes are hollow, permitting simultaneous suction. Two probe sizes are available: 3.3 mm and 3.8 mm.

Combined operation of the pneumatic and ultrasound units is desirable for certain hard kidney and bladder stones. In order to use the combined energy, the pneumatic and ultrasound handpieces must be mounted together to form a LithoClast® Master handpiece using an adjustment interface. The 1 mm pneumatic probe is inserted through the adjustment interface and through either the 3.3 mm or 3.8 mm ultrasound probe. The probes must be length-adjusted by turning the nut of the adjustment interface so that the tip of the pneumatic probe is flush with the tip of the ultrasound probe.

5. BASIS FOR SUBSTANTIAL EQUIVALENCE

The pneumatic module of the Swiss LithoClast® Master is substantially equivalent to the Swiss LithoClast®, which was previously cleared for intracorporeal fragmentation of ureteral and bladder stones under K951531 and for kidney stones under K963285. The ultrasound module of the Swiss LithoClast® Master is substantially equivalent to predicate ultrasonic lithotripters, including the Storz Ultrasound Lithotripters and the Richard Wolf Ultrasound Generator. The Swiss LithoClast® Master has the same intended use and similar technical specifications as compared with the predicate devices. Substantial equivalence has also been demonstrated by stone fragmentation testing. These tests confirmed that use of the Swiss LithoClast® Master results in

equivalent or faster fragmentation of a variety of standard artificial stone materials (ranging from soft to hard) when tested against various predicate ultrasound lithotripters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2001

Electro Medical Systems SA
% Ms. Sheila Hemeon-Heyer, J.D., R.A.C.
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K012445
EMS Swiss LithoClast® Master (a.k.a. Swiss LithoClast® Ultra) Lithotripter
Dated: July 31, 2001
Received: August 1, 2001
Regulatory Class: II
21 CFR 876.4480/Procode: 78 FFK

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012445

Device Name: SWISS LITHOCLAST® MASTER

Indications For Use:

The EMS Swiss LithoClast® Master is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter, and bladder.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012445

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)